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In re Application of  
Chada et al.  
Serial No.: 10/017,472  
Filed: December 7, 2001  
Attorney Dkt No.: INGN:097US

Decision on Petition

This letter is in response to the Petition under 37 C.F.R. 1.144, filed on December 28, 2004, petitioning the denial that claims 1 and 36 are proper linking claims. The delay in acting on this petition is regretted.

**BACKGROUND**

A review of the file history shows that the application was filed on December 7, 2001 with 67 claims.

A requirement for restriction was mailed to applicants on February 24, 2003, requiring the restriction of the 67 claims to one of four inventions. The claims were restricted as follows:

Restriction to one of the following inventions was required under 35 U.S.C. 121:

- I. Claims 1-43 are drawn to a method for inhibiting angiogenesis or endothelial cell differentiation comprising administering to a patient a nucleic acid expressing the human MDA-7 polypeptide. Classified in Class 514, subclass 44.
- II. Claims 1-6, and 13-41 are drawn to a method comprising administering to a patient a human MDA-7 polypeptide. Classified in Class 514, subclass 2.
- III. Claims 44-67 are drawn to a method for promoting an immune response comprising administering to a patient a nucleic acid expressing the human MDA-7 polypeptide and an antigen. Classified in Class 514, subclass 44, and class 424, subclass 184.1.
- IV. Claims 44-51, and 56-67 are drawn to a method for promoting an immune response comprising administering to a patient a human MDA-7 polypeptide and an antigen. Classified in Class 514, subclass 2, and class 424, subclass 184.1.

In the response dated March 17, 2003, applicants elected **without traverse** the claims of Group I, claims 1-43, directed to a method for inhibiting angiogenesis or endothelial cell

differentiation comprising administering to a patient a nucleic acid expressing the human MDA-7 polypeptide. In addition to applicants election, applicants submitted that claims 1 and 36 are proper linking claims covering both Groups I and II and that if claims 1 and 36 are found allowable, the Group II claims must be rejoined and considered for allowance.

On September 30, 2003, applicants election was acknowledged and applicants comments regarding claims 1 and 36 found non-persuasive and a first office action on the merits was mailed to applicants in which claims 1-4, 7-25 and 32-43 were rejected under 35 USC 12 first paragraph, claim 9 was rejected under 35 USC 112 second paragraph, claims 1-4, 7-25 and 35-43 were rejected under 102(e), claims 1, 7-9, 20-23, 36-41, 75 and 76 were rejected under 103(a) and claims 1-4, 7-25, 32, 35-43 and 77 were rejected under double patenting. Additionally, claims 1, 13, 18-23, 36-41, 75 and 76 were objected to because the claims encompass more than one invention. In response to this action, applicants amended claims 1, 15-17 and 36, added new claims 75-77, and argued the previous rejections.

On June 14, 2004, a final rejection was mailed to applicants in which claims 1-4, 7-25 and 32-43 were rejected under 35 USC 12 first paragraph, claims 1, 9, 15-17, 75 and 76 were rejected under 35 USC 112 second paragraph, claims 1-4, 7-25 and 35-43 were rejected 102(e) and claims 1, 7-9, 20-23 and 36-41 were rejected under 103(a) and claims 1-4, 7-25, 32, 35-43 and 77 were rejected under double patenting. Additionally claims 1, 13, 18-23 and 36-38 were objected to because the claims encompass more than one invention.

In response to the final rejection, applicants filed proposed amended claims 9, 15-17 and 39, arguments supporting applicants position and the instant petition in which applicants petition the denial that claims 1 and 36 are proper linking claims.

## DISCUSSION

The application, file history and petition have been considered carefully. Before the merits of the petition are addressed, a review of the claims, as pending and the claims under examination is warranted. Representative claims are shown below.

1. **(Previously presented) A method of inhibiting angiogenesis in a human patient in need of such treatment comprising administering to the patient an effective amount of a human melanoma differentiation antigen-7 (MDA-7) polypeptide or a nucleic acid expressing the human MDA-7 polypeptide in eukaryotic cells to inhibit angiogenesis.**
25. **(Original) The method of claim 1, wherein the MDA polypeptide comprises amino acids from 1 to 206 of SEQ ID NO:2.**
- 26.-31. **(Cancelled)**
32. **(Original) The method of claim 1, wherein the MDA polypeptide comprises amino acids from 182 to 206 of SEQ ID NO:2.**

36. (Previously presented) A method of inhibiting endothelial cell differentiation in a human patient comprising administering to the patient an effective amount of a human MDA-7 polypeptide or a nucleic acid molecule expressing the human MDA-7 polypeptide.
68. (Withdrawn) The method of claim 32, wherein the MDA polypeptide comprises amino acids from 175 to 206 of SEQ ID NO:2.
69. (Withdrawn) The method of claim 68, wherein the MDA polypeptide comprises amino acids from 150 to 206 of SEQ ID NO:2.
70. (Withdrawn) The method of claim 69, wherein the MDA polypeptide comprises amino acids from 125 to 206 of SEQ ID NO:2.
71. (Withdrawn) The method of claim 70, wherein the MDA polypeptide comprises amino acids from about 100 to about 206 of SEQ ID NO:2.
72. (Withdrawn) The method of claim 71, wherein the MDA polypeptide comprises amino acids from 75 to 206 of SEQ ID NO:1.
73. (Withdrawn) The method of claim 72, wherein the MDA polypeptide comprises amino acids from 49 to 206 of SEQ ID NO:2.

Text below is taken from the Final Office action mailed 15 June 2004 in which the Examiner stated that claims 68-74 are not proper dependent claims because they encompass rather than further limit the sequence in claim 32.

In the 2/2/04 response, Applicants indicated that the withdrawal of claims 68-74 from consideration is inappropriate because they depend from the elected species in claim 32. In response, claims 68-74 are drawn to various fragments of SEQ ID No: 2 that differ from the elected species in length or sequence composition and thus are distinct from the elected species. Applicants are reminded that the elected species is directed to the amino acids 182-206 of SEQ ID No: 2 as indicated in the response submitted 7/7/03. Moreover, it is noteworthy that the dependencies of claims 68-74 are improper because the sequences of claims 68-74 encompass rather than further limit the sequence recited in claim 32. Accordingly, it is appropriate to withdraw these claims from consideration by the Examiner pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim.

Claims 1, 15-17, and 36 have been amended, and claims 75-77 are newly submitted. Claims 1-25, 32-43, and 68-77 are pending. Claims 1-4, 7-25, 32-43, and 75-77 are under current examination.

An election of species requirement between the various ranges of SEQ ID No 1 was improper, as the ranges are not species, but rather varying scope of an invention which requires the fewest limitations, residues 182-206. Claim 32 is a generic claim. Claim 25, fully defined, is a species claim. Claims 68-74 recite gradations in scope between claims 32 (the broadest in scope) and claim 25, the narrowest). Because of the overlap in scope, compounded by the fact that both the broadest and narrowest claims have already been examined, the withdrawal of claims 68-74 was improper.

The finality of the Office action sent 15 June 2004 is hereby withdrawn. Claims 68-74 are joined to Group I and under examination.

Turning now to the merits of the petition, applicants argue that claims 1 and 36 are linking claims and as such, must be examined with any of the linked inventions.

Applicants are correct that claims 1 and 36 recite in the alternative the inventions of Groups I and II, however that does not make claims 1 and 36 "linking claims." Claims 1 and 36 recite limitations in the alternative and as such, are in Markush-type format. A linking claim for Groups I and II would be in the format of

Example of a Linking claim. A method of inhibiting angiogenesis in a human patient in need of such a treatment comprising elevating the amount of MDA-7 polypeptide in a patient to inhibit angiogenesis.

Should such a claim be present and allowable, then any claims which require all the features of the claim (such as those in the pending claim set) would ordinarily also be novel and obvious.

Claims 1 and 36 recite limitations in the alternative, in Markush-type format. MPEP 2173.05(h) states that

The materials set forth in the Markush group ordinarily must belong to a recognized physical or chemical class or to an art-recognized class. However, when the Markush group occurs in a claim reciting a process or a combination (not a single compound), it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is mainly responsible for their function in the claimed relationship, and it is clear from their very nature or from the prior art that all of them possess this property.

Even if the elected invention were in novel and unobvious, as evidenced by the outstanding rejection under 35 USC 112, for lack of enablement, it is not clear that the instant inventions possess a property in common that is mainly responsible for their function in the claimed method. As such, Group I and II do not qualify for election of species examination practice under 803.02.

Even if applicants can provide sufficiency for the Markush group, MPEP 803.02 then goes on to describe examination practice for Markush-type claims- if prior art is found on the elected

species then the provisional election takes effect and there is no requirement for the Office to extend the search to non-elected inventions.

Because claims 1 and 36 are not in condition for allowance, the request for examination of any "linked claims" is premature. Even if the members of the Markush group are disclosed in the specification to possess at least one property in common which is mainly responsible for their function in the claimed relationship and it is clear from their very nature or from the prior art that all of them possess this property, because the elected invention is not novel and unobvious, the request to have examination extended to other members of the Markush-type group is premature.

## DECISION

For these reasons, the petition under 37 C.F.R. 1.144 to request reconsideration of linking claim and withdrawal of claims directed to non-elected species is **GRANTED-IN-PART**.

The request to have Group II examined along with the elected invention of Group I is **DENIED** for the reasons set forth above.

The objection and withdrawal of claims 68-74 from examination and the finality of the Office action mailed 15 June 2004 is improper; rejoinder of claims 68-74 with the elected invention is **GRANTED**.

Finality of the Office action mailed 15 June 2004 is withdrawn.

The application will be forwarded to the Examiner for preparation of an Office action consistent with this decision and taking into account the responses filed since the last Office action.

Any request for consideration must be filed within two (2) months of the mailing date of this decision.

Should there be any questions regarding this decision, please contact Special Program Examiner Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600 or by Official Fax at 703-872-9306.



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